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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/720,278      | 05/24/2001  | Pieter Jacob Swart   | 702-002214          | 9397             |

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|               |              |
|---------------|--------------|
| EXAMINER      |              |
| TELLER, ROY R |              |
| ART UNIT      | PAPER NUMBER |
| 1654          |              |

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                         |  |
|------------------------------|-------------------------------|-------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>        | <b>Applicant(s)</b>     |  |
|                              | 09/720,278                    | SWART ET AL.            |  |
|                              | <b>Examiner</b><br>Roy Teller | <b>Art Unit</b><br>1654 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 March 2005.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4-15 and 22-39 is/are pending in the application.
- 4a) Of the above claim(s) 23-39 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 4-15, 22 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This office action is in response to the amendment, received 3/25/05, in which applicant cancelled claims 2-3 and 16-21, amended claims 1, 4-7, 9,10, 12, 14, and added new claims 23-39.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 23-39 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 4-15 and 22 are pending.

#### ***Claim Rejections - 35 USC § 112***

Claims 1, 4-15 and 22 are/stand rejected under 35 U.S.C. 112, first paragraph for the reasons of record which are restated below.

Claims 1-15 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for bovine lactoferrin and fluconazole for the treatment of *Candida* does not reasonably provide enablement for a medicament for treatment and/or prevention of infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors, said medicament comprising an active amount of a polycationic peptide or protein, and a buffer for maintaining the pH of treatable tissue within a preselected range. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The claimed invention is drawn to a medicament for treatment and/or prevention of infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors, said medicament comprising an active amount of a polycationic peptide or protein, and a buffer for maintaining the pH of treatable tissue within a preselected range.

The breadth of the claims is excessive with regard to claiming medicament for treatment and/or prevention of infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors, said medicament comprising an active amount of a polycationic peptide or protein, and a buffer for maintaining the pH of treatable tissue within a preselected range. Applicant has only provided guidance for the use of bovine lactoferrin and fluconazole for the treatment of *Candida*. Applicant have provided no guidance of any other medicament for treatment and/or prevention of infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors, said medicament comprising an active amount of a

polycationic peptide or protein, and a buffer for maintaining the pH of treatable tissue within a preselected range.

In absence of evidence to the contrary, it would not be expected that any and all polycationic peptides or proteins would act as a medicinal agent . Furthermore, it would not be predictable to the artisan which polycationic peptides or proteins would work in the present invention, nor would it be predictable to the artisan which pathologies could be treated with these polycationic peptides or proteins.

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the amended claims are more than adequately enabled by the specification. However, the examiner contends that the instant specification while being enabling for bovine lactoferrin and fluconazole for the treatment of *Candida* does not reasonably provide enablement for a medicament for treatment and/or prevention of infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors, said medicament comprising an active amount of a polycationic peptide or protein, and a buffer for maintaining the pH of treatable tissue within a preselected range.

***Claim Rejections - 35 USC § 102***

Claims 1, 4, 5, 8, 9, 11, 15 and 22 are/stand rejected under 35 U.S.C. 102(b) for the reasons of record which are restated below.

Claims 1, 2, 4, 5, 8, 9, 11, 15, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Steinberg (WO 97/18827).

The claimed invention is drawn to a medicament for treatment and/or prevention of infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors, said medicament comprising an active amount of a polycationic peptide or protein, and a buffer for maintaining the pH of treatable tissue within a preselected range.

Steinberg teaches compositions suitable for treating oral mucositis with antimicrobial peptides comprising a polycationic peptide (lactoferrin) and a buffer (citric acid) which discloses a final pH value of 7.0-7.2. Steinberg discloses vehicle and formulations containing 0.12- 2.0 mg/ ml (see, e.g., for example, page 5, lines 23-34, page 26, lines 9-10, page 37, lines 8-22, page 38, lines 18-22, page 60, lines 19-22, and page 62, claim 1).

Therefore, the reference is deemed to anticipate the instant claims above.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the cited reference neither teaches nor suggests the particular limitations recited in the amended claim 1. However, the examiner contends that Steinberg teaches compositions suitable for treating oral mucositis with antimicrobial peptides comprising

a polycationic peptide (lactoferrin) and a buffer (citric acid) which read upon the instantly claimed medicament.

***Claim Rejections - 35 USC § 103***

Claims 6, 7, 10, 12-14, and 22 are/stand rejected under 35 U.S.C. 103(a) for the reasons of record which are restated below.

Claims 3, 6, 7, 10, 12-14 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakabayashi et al (Antimicrobial agents and chemotherapy, 1998, vol. 42, no. 7, pp.-1587-1591) in view of Steinberg (WO 97/18827).

The claimed invention is drawn to a medicament for treatment and/or prevention of infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors, said medicament comprising an active amount of a polycationic peptide or protein, and a buffer for maintaining the pH of treatable tissue within a preselected range.

Wakabayashi beneficially teaches the effects of bovine lactoferrin (LF) coupled with fluconazole to inhibit hyphal growth of *Candida albicans* (see, e.g., for example, abstract, pp-1587 and pp-1589-1590). Wakabayashi does not teach a buffer for maintaining the pH of treatable tissue within a preselected range.

Steinberg beneficially teaches compositions suitable for treating oral mucositis with antimicrobial peptides comprising a polycationic peptide (lactoferrin) and a buffer which

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discloses a final pH value of 7.0-7.2 (see, e.g., for example, page 5, lines 23-34, page 26, lines 9-10, page 37, lines 8-22, page 38, lines 18-22, and page 62, claim 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to have combined the teaching of Wakabayashi effects of bovine lactoferrin (LF) coupled with fluconazole inhibit hyphal growth of *candida albicans* with the beneficial teachings of Steinberg, because Wakabayashi discloses the therapeutic effects of lactoferrin related compounds against candidiasis due to *C. albicans* are now being assessed.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that Wakabayashi does not teach or suggest the use of peptides alone to inhibit the growth of *C. albicans*. However, the examiner contends that Wakabayashi does teach that the peptide alone does have an effect, however slight.

### ***Conclusion***

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CHRISTOPHER R. TATE  
PRIMARY EXAMINER